K020605

MAR 8 2002

Section 2 - Summary of Safety and Effectiveness

(1) Contact Information

Vincent Cutarelli
Vice President, Regulatory Affairs
Telephone: (949) 768-1184 ext. 105
FAX: (925) 460-6084

(2) Company Information

Sanarus Medical, Inc.
5880 W. Las Positas Blvd., Suite 52
Pleasanton, CA 94588
Telephone: (925) 460-6080
FAX: (925) 460-6084

(3) Device Name

Sanarus Visica™ Treatment System

(4) Device Description

The Visica™ Treatment System consists of a control unit that controls one to eight single-use, disposable cryoprobes. The control unit is software-controlled and operates off standard 110/230 VAC wall power. A 486 IBM-compatible microprocessor serves as the host computer and a screen displays the status of the system. System control is accomplished either directly through keys on the console itself (e.g., 1-probe system) or through a remote control keypad (e.g., 4 and 8-probe system). The cryoprobes operate on the Joule-Thompson principle and the refrigerative capacity is limited only to the distal tip of the probe. The cryoprobes incorporate a thermocouple to measure temperatures at the probe tip. The thermocouple is mounted inside each cryoprobe tip and its signal is used to monitor and control some operations of the system. The control unit can also control one to eight independent temperature probes to monitor temperatures in surrounding tissues. The temperature probes are standard T-type needle thermocouples.

The system utilizes inert argon gas as a cooling agent. The system is available in 1, 4 and 8-Cryoprobe configurations. The performance characteristics and internal design of each model are equivalent. The primary differences are the number of valves to control the cryoprobes (e.g., 1-8), number of thermocouple inputs (e.g., 1-8) and the size of the outer case.

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(5) Indications for Use

The Sanarus Visica™ Treatment System is intended for use in general surgery, gynecology and oncology. The system is designed to destroy tissue by the application of extreme cold temperatures. In addition, the system is intended for use in the following indications:

General Surgery

- Ablation of breast fibroadenoma

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

(6) Name of Predicate or Legally Marketed Device

Endocare Cryocare® Surgical System

(7) Substantial Equivalence

The Sanarus Visica™ Treatment System is substantially equivalent to the Endocare Cryocare® Surgical System that was determined to be substantially equivalent on October 11, 2001 (reference K003811).

(8) Technological Characteristics

The Visica™ Treatment System has the same technological characteristics and performance specifications as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vincent Cutarelli
Vice President, Regulatory Affairs
Sanarus Medical, Inc.
5880 West Las Positas, Suite 52
Pleasanton, California 94588

Re: K020605
Trade Name: Visica™ Treatment System
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: February 22, 2002
Received: February 25, 2002

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020605

Indications For Use

510(k) Number: K020605

Device Name: Visica™ Treatment System

Indications for Use: The Visica™ Treatment System is intended for use in general surgery, gynecology and oncology. The system is designed to destroy tissue by the application of extreme cold temperatures. In addition, the system is intended for use in the following indications:

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Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Concurrence of CDRH, Office of Device Evaluation (ODE):

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020605

Prescription Use: X
(Per 21 CFR 801.109)